# Declaration of Boles

# Exhibit A

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF TENNESSEE**

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| **PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, MEMPHIS CENTER FOR REPRODUCTIVE HEALTH, KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH, FEMHEALTH USA, INC., d/b/a CARAFEM, and AUDREY LANCE,** | ) | |
| **Plaintiffs,** | ) | |
| **v.** | ) | **Case No. 3:20-cv-00740** |
| | ) | **Judge Campbell** |
| **HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity; LISA PIERCEY, M.D., Commissioner of the Tennessee Department of Health, in her official capacity; RENE SAUNDERS, M.D., Chair of the Board for Licensing Health Care Facilities, in her official capacity; W. REEVES JOHNSON, JR., M.D., President of the Tennessee Board of Medical Examiners, in his official capacity; HONORABLE AMY P. WEIRICH, District Attorney General of Shelby County, Tennessee, in her official capacity; GLENN FUNK, District Attorney General of Davidson County, Tennessee, in his official capacity; CHARME P. ALLEN, District Attorney General of Knox County, Tennessee, in her official capacity; and TOM P. THOMPSON, JR., District Attorney General for Wilson County, Tennessee, in his official capacity,** | ) | |
| **Defendants.** | ) | |

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**DECLARATION OF DR. BRENT BOLES**

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I, Brent Boles, M.D., pursuant to the provisions of 28 U.S.C. § 1746, do hereby declare as follows:

1. I am Brent Boles, a practicing obstetrician and gynecologist in Murfreesboro, Tennessee.
2. I have been board certified for more than twenty years and have been in practice in Murfreesboro for the last fifteen years. I teach at the University of Tennessee School of Medicine and the Meharry College of Medicine. I also am a member of the Medical Advisory Board for both Heartbeat International and Abortion Pill Reversal (or Rescue). ("APR"). I have attached my curriculum vitae as *Exhibit 1*.
3. On March 10, 2020, I testified before the Tennessee General Assembly, specifically the House Health Committee, on HB 2568 (the provisions of which were subsequently enacted as part of HB2263/SB2196). At that hearing, an amendment was offered to the bill that would require abortion providers to inform a patient seeking a medication abortion that, if the patient changes her mind after taking the first pill, she may be able to avoid, cease, or reverse the effects of that first pill in the two step abortion pill series, particularly if she seeks assistance fast enough. I testified about the need to provide women with this information that there is a medical regime that is both safe and potentially effective in reversing the effect of the first pill. Attached as *Exhibit 2* is a true and correct transcription by a court reporter of my testimony as part of this bill's Legislative History. (*See* Ex. 2, p. 4, l. 16—p. 45, l. 25).
4. The abortion pill medication treatment involves two pills: Mifeprex or mifeprestone or RU486 (it goes by three different terms), and Cytotec or misoprostol. (*See generally* Ex. 2, p. 5, l. 10—p. 6, l. 1).

5. The first pill, mifepristone, is a progesterone blocker. Progesterone is a hormone that is vital to the success of a pregnancy throughout the course of a pregnancy. When the action of progesterone is interfered with in the first trimester by Mifepristone, the drug may cause loss of the embryo or the fetal life, and in some cases expulsion of the pregnancy tissue.
6. Mifepristone alone is not always effective in ending a pregnancy. A study of data published by Dr. Daniel Grossman (an abortion provider) found that as few as 8% of pregnancies survived when only mifepristone was administered. (*See* Ex. 2, p. 22, l. 19—p. 23, l. 13).
7. The second pill, Cytotec, ensures that the tissue is expelled and is given twenty-four to forty-eight hours after the first pill.
8. When a patient has changed her mind and has taken the mifepristone but has not yet taken the Cytotec, administering natural progesterone may result in preventing loss of the fetal life in as many as sixty-eight percent (68%) of pregnancies. (*See* Ex. 2, p. 5, l. 10—p. 6, l. 13). The administration of natural progesterone has not been shown to have any increase in birth defects or in adverse effects for women – and is safer that taking the mifepristone and simply choosing to not take the Cytotec. (*See generally* Ex. 2, p. 6, l. 14—p. 7, l. 19).
9. As part of the Abortion Pill Reversal network, I am on call to help advise and assist mothers who take the first abortion pill, change their mind, want to try to save their baby, and find the network (typically through their own searching). (*See generally* Ex. 2, p. 27, l. 4—p. 28, l. 5).
10. I do not keep a list, but I would estimate that I have prescribed natural progesterone to more than 20 women who wanted to reverse their abortion processes – some right here in Tennessee who then had healthy babies. The Abortion Pill Reversal network has tracked more than 1,000 living, healthy babies with no increased risk of birth defects who have

been delivered because patients interacted with the APR network. (*See* Ex. 2, p. 13, l. 16—p. 15, l. 10; p. 44, l. 14—p. 45, l. 17).

11. I have even delivered some of those babies myself and have seen firsthand how the abortion pill process can be reversed in some situations.

12. Published studies, such as in 2007, 2012, and 2018, support the efficacy of this progesterone treatment.[1] (*See* Ex. 2, p. 7, l. 6-19; p. 22, l. 19—p. 23, l. 13; p. 30, l. 15—p. 31, l. 22). The largest case study in 2018 included 754 patients. Those who took the currently recommended progesterone regimen had a 68% success rate in reversing the abortion process—with no increased outcomes that were unfavorable for the mother or for the baby.

13. This method of progesterone treatment has not been shown to cause any increase in adverse effects for the women who choose to pursue the treatment.

14. Further, this method of progesterone treatment has not been shown to cause any increase in birth defects for the fetuses of the women who choose to pursue the treatment.

15. A study released by the American College of Obstetrics and Gynecology, which was authored by Dr. Creinin (an abortion physician), unsuccessfully attempts to support a claim, based upon only a series of 12 patients, that attempting to reverse the abortion process is neither safe nor effective. Analysis of the three patients who experienced bleeding issues (out of the twelve total patients) showed that two of those who took mifepristone and a placebo needed hospital treatment, while the one who received progesterone treatment, upon arriving at the hospital, was found to not need surgical

[1] *See* Delgado G, Davenport M. Progesterone use to reverse the effects of mifepristone. Annals of Pharmacotherapy. 46 2012 Dec;46(12):e36.; Delgado G, et al. A case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone. Issues in Law and Medicine (2018) 33(1): 21- 31.

intervention or a blood transfusion for the deceased embryo she spontaneously passed. (*See* Ex. 2, p. 8, l. 1—p. 10, l. 2; p. 11, l. 3—p. 13, l. 12; p. 15, l.23—p. 17, l. 10; p.42, l.2—22).

16. The American Medical Association's Code of Ethics in sections 1.1.1 and 1.1.3 require the physician treating the patient to give an accurate and complete disclosure of information in the informed consent process and to do so in a manner that it is not self-serving to the physician's own interests. (*See* Ex. 2, p. 10, l. 1—12).

17. With a success rate that may be as high as 68%, women need to be told of the possibility that progesterone treatment may assist in reversing their abortion process after taking the mifepristone if they so choose. To not inform them of this possibility is to not give them a full and complete disclosure in the informed consent process (and particularly if the women inquires after taking the first pill) and is a violation of both sections of the AMA's Code of Ethics. (*See* Ex. 2, p. 23, l. 14—23).

18. Tennessee's recently passed abortion law (HB2263/SB2196) is an important step in ensuring that mothers receive complete and accurate information that the abortion process "*may* be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone . . . ." (emphasis added).

I declare under penalty of perjury that the foregoing is true and correct. Executed by me on the ___th day of September, 2020, in Murfreesboro, Tennessee.

C. BRENT BOLES, M.D. MD 9/14/2020

# Curriculum Vitae of Boles

# Attachment 1

C. Brent Boles, M.D.
Covenant Healthcare for Women, P.L.L.C.

1800 Medical Center Parkway
Suite 325
Murfreesboro, Tennessee 37129
615-867-0034

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Professional History

- Physician and Owner, Covenant Healthcare for Women, P.L.L.C., January, 2006 to present
- Medical Director of Portico (local crisis pregnancy center) 2008 to present
- Vice Chief of Obstetrics and Gynecology, Middle Tennessee Medical Center, Murfreesboro TN, 2007-2008
- Chief of Obstetrics and Gynecology, Middle Tennessee Medical Center, Murfreesboro TN, 2009-2010
- Associate Clinical Professor in the University of Tennessee Department of Emergency Medicine at Saint Thomas Rutherford Hospital, July 2015 to present
- Associate Clinical Professor and Assistant Residency Director for the Saint Thomas Rutherford Campus, Department of Obstetrics and Gynecology, Meharry College of Medicine, 2006 to present
- Clinical Instructor for the University of Tennessee Physician Assistant School, 2016 to present
- IC Research, Principal Investigator, 2018 to present
- OB/GYN Associates, July 2005-December 2005
- Murray Woman's Clinic, July 1996-June 2005
- Middle Tennessee Medical Center Laborist Program Director, November 2006-March 2011
- Certified on the Da Vinci Xi robotic surgery platform
- Member of the Medical Advisory Board for Heartbeat International
- Member of the Medical Advisory Board for Abortion Pill Reversal

Educational History

- Certified by the American Board of Obstetrics and Gynecology, November 1998 to present
- Chief Administrative Resident, University of Louisville School of Medicine, Department of Obstetrics and Gynecology, July 1995 - June 1996
- Internship and Residency, University of Louisville School of Medicine, Department of Obstetrics and Gynecology, July 1992-June 1996
- Doctor of Medicine, University of Louisville School of Medicine, August 1988-May 1992
- Bachelor of Science in Biology, Murray State University, August 1984-May1988

Licensure

- Tennessee Board of Medical Examiners, 2004 to present
- Kentucky Board of Medical Licensure, 1993 to 2011
- Drug Enforcement Agency Registration, 1993 to present

Memberships

- American Institute of Ultrasound in Medicine, 1998 to 2005
- International Society for Clinical Densitometry, 1998 to 2005
- Christian Medical and Dental Association
- American Association of Pro-Life Obstetricians and Gynecologists

Awards

- Professor of the Year Award, University of Tennessee Health Science Center, Saint Thomas Rutherford Department of Emergency Medicine, 2016
- Meharry Appreciation Award, 2009
- Foundation Award for Clinical Excellence, Department of Obstetrics and Gynecology, University of Louisville School of Medicine, 1994
- Best Clinical Teacher Awards, University of Louisville School of Medicine, 1993, 1994, 1996

- Clinical Research Awards, University of Louisville School of Medicine, Department of Obstetrics and Gynecology, 1995 and 1996
- Laparoscopic Skills Award, University of Louisville School of Medicine, Department of Obstetrics and Gynecology, 1995
- Presidential Scholarship Award, Murray State University, 1984 to 1988

# House Health Committee HB2568

# Attachment 2

**LEGISLATIVE HISTORY - HOUSE HEALTH COMMITTEE (HB2568)**

# AUDIO RECORDING

## March 10, 2020

VETERAN COURT REPORTING
D. Rochelle Koenes, RPR, LCR
veterancourtreporting@gmail.com
(931) 919-8932

# LEGISLATIVE HISTORY-HOUSE HEALTH COMMITTEE (HB2568)

AUDIO RECORDING

of

HOUSE BILL 2568

dated

March 10, 2020

Veteran Court Reporting
veterancourtreporting@gmail.com
D. Rochelle Koenes, RPR, LCR
P.O. Box 3593
Clarksville, Tennessee 37043
(931)919-8932

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P R O C E E D I N G S

(WHEREUPON, the following is transcribed from an audio recording as follows:)

IN THE HOUSE HEALTH COMMITTEE

March 10, 2020

(WHEREUPON, On the above date, there came up for consideration in the House Health Committee of the Tennessee House, House Bill 2568, sponsored by Representative Faison, and discussion pertaining to this bill was as follows:)

MR. CHAIRMAN: And with that we have a pretty extensive calendar today, and I would like to get us to Item Number 1, House Bill 2568 by -- Representative Faison you are recognized.

REPRESENTATIVE FAISON: Good morning, Committee, Mr. Chairman.

MR. CHAIRMAN: Do you have a motion?

UNIDENTIFIED SPEAKER: Second.

REPRESENTATIVE FAISON: Committee, House Bill 2568 is a bill that I brought in the attempt for if a young lady has decided to go get an abortion, and it's the abortion where they give a

pill -- they typically give two pills -- one you take at the clinic and one 48 hours later that you take. If they have -- for whatever reason, they change their mind, I want them to know that there's a possibility that they can get that reversed and this bill would have an -- abortion clinic providers put up a posting that there is a possibility that you can reverse it and also let them know if they change their mind that they can reverse it.

MR. CHAIRMAN: You have an amendment on the bill?

REPRESENTATIVE FAISON: I do, yes, sir. And the Amendment Drafting Code is 0148 -- -14982.

MR. CHAIRMAN: Drafting Code 014982. I have a motion and a second.

Okay. The amendment is properly before us. Can you give us comments on the amendment?

REPRESENTATIVE FAISON: Just exactly what I just said.

MR. CHAIRMAN: Do we have questions from the committee on the amendment? If not, we do have somebody -- we were supposed to have two people here to testify on this -- on the amendment. We can either take questions now or we can go out of session.

I think only one person has shown up to testify. But do we have any questions before we go out of session?

Representative Clemmons, do you have a question?

REPRESENTATIVE CLEMMONS: I was just going to recommend that we go out of session first and then defer questions until after that.

MR. CHAIRMAN: All right. Seeing none, without objection, we will go out of session.

Our first -- I believe, maybe, the only person that we have here that may testify, Dr. Brent Boles, if you can come up and please make sure the mic is on. Tell us who you are and who you're with.

DR. BOLES: Good morning. My name is Brent Boles. I am an OB/GYN who's been board certified for more than 20 years and has been in practice in Murfreesboro for the last 15 years. In addition to my private practice and academic teaching appointments that I have with both the University of Tennessee School of Medicine and the Meharry College of Medicine, I am a member of the medical advisory board for both Heartbeat International and Abortion Pill Reversal.

I'm here this morning to speak in support of the representative's bill that would require abortion providers to simply notify a patient during the informed consent process that if they choose to change their mind after they have taken the first pill, that there is a medical regimen that is both safe and effective that has the potential to reverse the effects of the first pill in the abortion pill series.

The history of abortion pill medication treatment is that in the year 2000 the Food and Drug Administration approved a drug produced by a pharmaceutical company called Danco. That drug is known as Mifeprex for mifepristone or RU486. There are three different terms by which it is called.

This pill is a progesterone blocker. Progesterone is a hormone that is vital to the success of a pregnancy throughout the course of the pregnancy. And when the action of progesterone is interfered with in the first trimester, the mifepristone will cause loss of the embryo or the fetal life. And then in some cases, cause expulsion of the pregnancy tissue. In order to ensure that the tissue is expelled, a second medication called Cytotec is given 24 to 48 hours

after the first pill is dosed.

Basic principals of pharmacology have led us to discover that when a patient has changed her mind and has taken the mifepristone but has not yet taken the Cytotec, that if you simply administer natural progesterone, you have as high as a 68 percent success rate in preventing loss of the fetal life.

This method of treatment has not been shown to cause any increase in adverse effects for the women who choose to pursue this. In fact, it is more safe than taking the mifepristone and simply not using the Cytotec.

This was discovered first in 2007 by a physician named Matthew Harrison in South Carolina who was approached by a patient who had taken the mifepristone and desired to change her mind. He studied the pharmacology of the drug and gave her a prescription of progesterone and she later delivered a living baby at term. At the same time, Dr. George Delgado on the west coast was approached with a similar problem by a similar patient and found similar results.

The first case series that was published that reported on this was released in

2012. It was a small case series and that is the criticism that the abortion industry has of this process. They claim that such a small case series with only six patients cannot be used to draw any conclusions.

The truth of the matter is that case series showed a two out of three success rate of the six patients who pursued reversal. Four delivered living babies later in their pregnancy. That is not the only study, but the abortion industry would like for you to believe that it was. There have since been at least three other published studies, the largest one of which included 754 patients in whom the current recommended regimen had a 68 percent success rate at reversing the abortion process with no increased outcomes that were unfavorable for the mother or the baby. There were no birth defects. There were no other issues reported in that study.

Another study is about to begin, and I will be one of the principal investigators in this study that will compare methods of administering the progesterone. So there's ongoing research that I believe will continue to demonstrate both the efficacy and the safety of this medication.

The recent study that was released by the American College of Obstetrics and Gynecology authored by Dr. Creinin, who is an abortion physician, makes the claim, based on a series of only 12 patients, that attempting to reverse abortion is neither safe nor effective.

I find it interesting that the abortion industry's criticism of the Delgado case series in 2012 focused on the fact that it only had a small number of patients and you can't draw conclusions from that, but now they expect us to draw conclusions from a study that also has a small number of patients, namely only 12. They claim from this study that it is -- that you -- it is not safe for the patient to take the mifepristone and then not complete the process with the Cytotec.

They make this conclusion because three of the twelve patients in that study had to go to the emergency room for bleeding. The truth of the matter when you break down those numbers, there were six patients in the study who took mifepristone and placebo, meaning they were not being treated for attempted reversal, the other six patients took mifepristone and progesterone in the current recommended regimen.

Of the six patients who took progesterone, five of them had ongoing pregnancies. So the success rate was five out of six, more than 80 percent. One of those patients was taken to the emergency room because she was worried about the amount of bleeding that she had. But when she arrived at the emergency, her embryo was no longer living and she spontaneously passed the tissue without requiring a DNC or any other surgical intervention and without requiring a blood transfusion. The other two patients who required treatment in the emergency room, both were taken to the emergency room because of heavy bleeding. Both required surgical aspiration of the pregnancy tissue, and one of the two required a transfusion.

So the real conclusion that you can draw from the Creinin study is that it is not safe to take mifepristone and then decide not to take the Cytotec. So when a patient changes her mind, if she can't get help and can't figure out how to reverse the process and decides not to take the Cytotec, then that is dangerous for her. But the other conclusion is that when she takes the -- when she is made aware of the reversal regimen and takes it, it is not only safe but it is effective at a

minimum 68 percent of the time and perhaps as much as more than 80 percent of the time.

The American Medical Associations Code of Ethics in sections 1.1.1 and 1.1.3 require the physician treating the patient to give a full, accurate, and complete disclosure of information in the informed consent process and do so in a way that is not self-serving the patient's own interest -- or the physician's own interest. Refusing to tell patients that a reversal regimen is possible is a violation of both sections of the AMA code of ethics.

MR. CHAIRMAN: Thank you for that testimony.

Do we have questions while we are --

Representative Dixie, you are recognized.

REPRESENTATIVE DIXIE: Thank you, Mr. Chairman. I just have a couple of quick questions.

You gave us a lot of stats about studies. Obviously, most studies say that they are extensive and hundreds, if not thousands of patients.

Why was this study stopped at six

patients?

DR. BOLES: Which study?

REPRESENTATIVE DIXIE: Well, you said earlier that there was a study that had six patients that went through and they took both and then the other one had the placebos. Why was it only stopped at twelve people?

DR. BOLES: You're referring to the Creinin study, which had six patients in each arm. There were twelve patients in the study. Their initial plan was to enroll 40. It is typical when you're conducting a study and you see what you believe are adverse outcomes to stop the study early if there are indications that it is dangerous to the patient. The stated reason for stopping the study was that three patients had to -- three out of twelve had to be taken to the emergency room for bleeding.

REPRESENTATIVE DIXIE: Really, three out of six because six only had placebos.

DR. BOLES: There were twelve patients total. One of the patients who went to the ER for bleeding came from the progesterone group and two of them came from the placebo group. So the study at that point had twelve patients enrolled with a plan

to enroll 40. But they stopped because three of the twelve were evaluated for bleeding.

REPRESENTATIVE DIXIE: I want to circle back to make sure I got your answer correct.

DR. BOLES: Okay.

REPRESENTATIVE DIXIE: You said that it was stopped because they thought it would have adverse effects going forward.

DR. BOLES: Yes. They stopped the study because three of the twelve patients had to be evaluated for bleeding. When you evaluate which patients had to be evaluated for bleeding, only one was from the progesterone group. And she did not need a blood transfusion and she did not need surgery. The patients who had to have interventions -- surgery and/or a blood transfusion -- came from the group that took the Mifeprex but did not take the progesterone to attempt to reverse.

REPRESENTATIVE DIXIE: So based on the study that you quoted that you gave us right here, this doesn't sound like it's safe and effective if it was stopped for adverse reasons.

DR. BOLES: It was stopped because two of the patients who did not take the treatment had

to have a blood transfusion or surgery. Those were patients that were not in the treatment arm. They were in the placebo arm. And the reason for stopping the study -- if you want to know what I believe that you can conclude based on that is they didn't like the data. The adverse outcomes that required intervention were in the group that did not get the reversal treatment. And the reversal treatment, which they claim is not effective in their six patients was shown to be more than 80 percent effective. I believe that's why the study was stopped.

MR. CHAIRMAN: Representative Dixie?

REPRESENTATIVE DIXIE: One last question.

You did mention that there were babies delivered after this. Has there been any studies or any follow up on how the babies are doing emotionally, physically? Any kind of side effects since then?

MR. CHAIRMAN: Dr. Boles, you're recognized.

DR. BOLES: The abortion pill reversal mechanism involves a -- there's a website that patients go to. Abortion providers don't tell

patients about the availability of this regimen. The people who find it go to their smart phone or their iPad and they go to Google and they say, "Can an abortion pill be reversed?" The thing that pops up is abortionpillreversal.com, which is a free, nonprofit service that is provided to patients with a toll-free 24-hour-a-day hotline.

Through that hotline, the patients who are truly interested in pursuing reversal are connected with one of over 500 physician providers across the country who will prescribe this regimen for them. I'm one of those providers. The statistics on the outcomes of the patients who use that mechanism has been tracked and there are currently more than a thousand living, healthy babies with no increased risk of birth defects who have been delivered because patients have interacted with the abortion pill reversal hotline.

In fact, one other positive thing, other than saving the life of the baby, the progesterone supplementation early in the pregnancy according to our statistics of more than a thousand deliveries accomplished are that, when you look at the preterm delivery rates of those babies, the general preterm delivery rate in the United States

is about 10 percent. And for patients who use the abortion pill reversal regimen and are successful, the preterm delivery rate is under 3 percent.

So not only are there no increase in birth defects and no increase in bad maternal outcomes, there is a decrease in the risk of preterm delivery, which is one of the biggest problems in children's health care in the country and the number one cause of cerebral palsy in America.

MR. CHAIRMAN: Representative Dixie?

REPRESENTATIVE DIXIE: I promise this is my last question.

DR. BOLES: It's okay.

REPRESENTATIVE DIXIE: Currently, are there any laws right now that prohibit you from doing what you're doing now as far as giving these two pills for this procedure?

DR. BOLES: No.

REPRESENTATIVE DIXIE: There's no -- okay. That's my last question.

Thank you. Thank you, Mr. Chairman.

MR. CHAIRMAN: Thank you.

To clarify on his point on this, the study that had the six patients that got a placebo

and six patients that got progesterone as the second pill, did they -- if they gave Cytotec, that was not part of those 12 patients; is that correct?

DR. BOLES: That's correct. It was not.

MR. CHAIRMAN: And so what you can take from that study would be that, if a patient was not adequately informed and they were not compliant with their second pill that a portion of those may end up in the ER but a significant portion would -- could carry the baby to term and even a more significant portion of those if the reversal pill was given could carry that to term; is that correct?

DR. BOLES: Could you say that again? I want to be sure I got it clearly.

MR. CHAIRMAN: Okay. So let's separate them into three groups. The first group is they get the abort- -- the first pill, mifepristone.

DR. BOLES: Yes.

MR. CHAIRMAN: And then they are compliant with the Cytotec then they would abort?

DR. BOLES: Yes.

MR. CHAIRMAN: If they were not compliant, that would be the equivalent of the placebo group and a significant portion of those could carry to term. But based on that minor study,

a portion of those may end up in the ER and those are the ones that got the blood transfusions and had to have the evacuation.

DR. BOLES: That is correct.

MR. CHAIRMAN: But if the patient was informed that if they came back and had the reversal pill, still, a small percentage may miscarry at that point in time but a significant portion of those would carry to term?

DR. BOLES: That's correct.

MR. CHAIRMAN: All right. Thank you.

Representative Clemmons, you're recognized.

REPRESENTATIVE CLEMMONS: Thank you, Mr. Chairman.

And thank you for being here today.

DR. BOLES: Thank you.

REPRESENTATIVE CLEMMONS: I just want to get some background.

You're an OB/GYN, you say?

DR. BOLES: Yes.

REPRESENTATIVE CLEMMONS: And how many years have you been in practice?

DR. BOLES: I graduated from medical school in 1992; so 28 years as a physician. The

first four of those were my residency; so 24 years in independent practice.

REPRESENTATIVE CLEMMONS: And during that time frame, about how many abortions have you performed?

DR. BOLES: None.

REPRESENTATIVE CLEMMONS: And are you not trained to do those or is that a --

DR. BOLES: I chose not to participate in the abortion training.

REPRESENTATIVE CLEMMONS: And this -- these pills that we are discussing here, are they FDA approved?

DR. BOLES: They are FDA approved, yes.

REPRESENTATIVE CLEMMONS: And how long have they been FDA approved?

DR. BOLES: Since 2000.

REPRESENTATIVE CLEMMONS: Since 2000?

DR. BOLES: Yes.

REPRESENTATIVE CLEMMONS: So you discussed the clinical trials in 2012, what were the trials before that were approved by the FDA?

MR. CHAIRMAN: Dr. Boles, you're recognized.

DR. BOLES: The FDA trial that was

conducted by Danco, the pharmaceutical company, was the first trial and that resulted in the FDA approval. To my knowledge, there have been no further FDA sanctioned trials. The FDA did in the last few years based on data submitted by Danco broadened the indication for which mifepristone can be given. In 2000, they approved it for up to seven weeks and then a few years ago they broadened that to ten weeks. But that was not based upon any other brand new randomized trial.

The other trials which I discussed, the studies which were case series reports and other studies, were not conducted by the Food and Drug Administration or by Danco Pharmaceuticals. They were conducted by the people who have developed the reversal regimen.

REPRESENTATIVE CLEMMONS: So with the reversal regimen itself, is that process -- I'm trying to get my head around the peer review depth or the depth of peer review on the reversal process itself as opposed to the separate pills.

DR. BOLES: The first study, the limited case series of only six patients that was published in 2012, was published in a peer review journal called The Annals of Pharmacotherapy. The largest

series of 754 patients who were evaluated in a more structured manner was published in a peer review journal called Issues in Law and Medicine.

REPRESENTATIVE CLEMMONS: Where was that?

DR. BOLES: Issues in Law and Medicine.

REPRESENTATIVE CLEMMONS: That's the actual group?

DR. BOLES: That's the name of the journal.

REPRESENTATIVE CLEMMONS: So the pills themselves have been approved, but is the process itself and the rate of success of the reversal, is that approved in any way by the FDA, or is it just standalone?

MR. CHAIRMAN: Dr. Boles, you are recognized.

DR. BOLES: The Food and Drug Administration does not require that prescription medications be used only for their FDA approved indications. Most prescriptions that you take may be given for what are considered off-label indications. Once a medication has been proven to be safe and effective for the condition for which it was originally approved, it can be used for any

other purpose for which it was approved or for which it has been shown to be effective.

Progesterone itself, natural progesterone has been used in women's health for over 50 years. If there are women in this room that are on a birth control method that's prescribed that is anything other than a copper IUD, they have a form of prescription progesterone in their system right now. Menopausal women receive progesterone. Progesterone has been approved for use in pregnancy and is considered Category B and has been shown to have no adverse outcomes for use in pregnancy. In fact, is widely used to prevent repetitive miscarriages and preterm labor. So the medication does have approval for use. There is not a problem with off-label use.

Have I answered your question?

MR. CHAIRMAN: Representative Clemmons, you are recognized.

REPRESENTATIVE CLEMMONS: Thank you, Mr. Speaker.

I'm not sure you have. So what I'm getting at here is we're asking trained medical professionals to give patients advice about something or recommend something or a process or

give women false hope, perhaps, about a process that may or may not work, and I don't hear you saying that there is an overwhelming amount of peer review study on the success rate of this process.

You discussed a 66 percent approval rate of a very small pool. That gives me pause when we are mandating creating a Class E felony for doctors who don't do this. But a medical professional -- why would they ever give a patient who is in an emotionally fragile state false hope about something when the success rate is, A, so low and, B, not substantively tested or thoroughly.

In your 20-plus years of practicing medicine, how often have you given a patient advice or a recommendation based on a test that was six people deep with a two-thirds success rate?

MR. CHAIRMAN: Dr. Boles, you're recognized.

DR. BOLES: You're forgetting the study that I quoted that has 754 patients still with a 68 percent success rate. That's almost three out of four. Where if they don't get treatment, their rate is pretty close to zero. Because without -- if you take the mifepristone but do not take progesterone, even if you don't take the Cytotec, the fetal

survival rate is as low as 8 percent. And that's a report not from me or a pro-life physician. That's a report of analysis of the data that was published by Dr. Daniel Grossman who is an abortion provider.

And he wrote in a study that review of the data shows that when a patient takes mifepristone, the fetal survival rate can be as low as 8 percent. Our study of 754 patients published in a peer review journal shows that the current regimen that we recommend has a 66 to 68 percent success rate. So I don't believe you can call it false hope to increase the fetal survival from 8 percent to 68 percent.

And I don't believe that when a patient changes their mind and you refuse to respect their choice -- because that's what the abortion providers tell us. This issue is all about, I think, the patient's choice. If the patient chooses to change her mind and is asked specifically by a patient -- and is asked -- the patient specifically asks the abortion provider if anything can be done and they're told "no," then I don't believe that is ethical.

MR. CHAIRMAN: Representative Clemmons, you are recognized.

REPRESENTATIVE CLEMMONS: Thank you, Mr. Speaker.

And, you know, you just told my colleague over here that doctors can currently do this. So you saying that we're refusing to respect a patient's choice, I don't know if that's occurring right now if you say it's already allowed to take place.

And my final question is do you intend to perform any abortions in the future?

MR. CHAIRMAN: Dr. Boles.

DR. BOLES: No, I do not.

MR. CHAIRMAN: Representative Clemmons.

REPRESENTATIVE CLEMMONS: So you will never be doing what you're asking other doctors to do today?

DR. BOLES: I'm not asking any doctor to perform an abortion. I'm asking that the abortion providers be required to answer the question truthfully when a patient looks at them and says, "I'm sorry that I took this. I want to change my mind." I have delivered babies who have been successfully reversed. I currently have two patients that I'm following that I started on the reversal protocol within the last three weeks.

I spoke to some of those patients yesterday in preparation for this hearing today. I told them that I would be coming here to testify and I asked them -- I said, "Would you be in support of a law that would require the abortion provider to inform you at the time you take the Mifeprex that, if you change your mind, there's a way to reverse it?" They all said, "Yes."

Patients who have been through this process support this kind of legislation because the other universal thing that I know in asking every patient that the hotline has referred to me that I ask them, "Did you ask your abortion provider if there was a possibility of reversing this?" And every single patient who asks that question was told "no." Some of them were, in fact, told that, if they didn't complete the process, their baby would have birth defects and that's dishonest because the FDA in it's pursual of the approval for Danco's application asked Danco "Are there any birth defects in the babies that survive this process?" And Danco said "no."

REPRESENTATIVE CLEMMONS: And Danco --

MR. CHAIRMAN: Representative Clemmons, you are recognized.

REPRESENTATIVE CLEMMONS: And who is Danco again?

DR. BOLES: Danco is the pharmaceutical company that produces Mifeprex.

REPRESENTATIVE CLEMMONS: That's (indiscernible, simultaneous crosstalk) off the medication?

DR. BOLES: I'm sorry?

REPRESENTATIVE CLEMMONS: No further questions.

MR. CHAIRMAN: Okay.

Representative Byrd, you are recognized.

REPRESENTATIVE BYRD: Thank you, Mr. Chairman.

Is there any research that has been done that shows what percent of women, if they had known about this reversal process, would have not followed through with abortion?

DR. BOLES: Could you repeat that?

REPRESENTATIVE BYRD: Yeah. Is there any research that has shown what percentage of women, if they had known about this reversal process, would have not followed through with the abortion?

MR. CHAIRMAN: Dr. Boles, you are recognized.

DR. BOLES: I'm not sure that I can answer that. There's not information that gives us a specific percentage of the number of women who regret what they have done after they take the pill. What I have learned in talking to many of these patients over the three or four years that I have been part of the Abortion Pill Reversal network is that there are women who do take the pill and immediately regret it.

In fact, one that I talked to less than two weeks ago was -- had found the hotline on an internet search and was calling it begging for help less than an hour after taking the first pill in the series.

So can I tell you what the percentage of women who take medication abortion pills then regret it? No. I can't tell you that. Can I tell you that there are a decent number of people that do? Absolutely. The hotline gets at least a dozen phone calls a day and on busier days of the week sometimes considerably more than that. So there are patients who seek this out and they find it not because they are informed of it at their abortion

provider but because they find it themselves.

So we have no way of knowing how many people didn't find this method and simply completed the abortion process even though they regretted it. There's no way to know that information.

MR. CHAIRMAN: Representative Byrd, you are recognized.

REPRESENTATIVE BYRD: No further questions.

MR. CHAIRMAN: Okay.

Chairman [sic] White, you are recognized.

REPRESENTATIVE WHITE: Thank you, Chairman.

Just for clarity on my part. What is the time period between administration of the mifepristone and the Cytotec if you're going through the complete process?

DR. BOLES: 24 to 48 hours.

REPRESENTATIVE WHITE: 24 to 48 hours.

And I think you said this three times, but I just want to make sure I understood correctly.

If a dose of mifepristone is administered, it can be reversed with a regimen of

progesterone. But without the progesterone, then it can be harmful to the woman unless she completes the Cytotec?

DR. BOLES: Yes. So the woman who changes her mind after taking the mifepristone and decides that she's not going to take the Cytotec and hope for the best because she doesn't know there's a better option, she is at risk. So when the patients leave the abortion clinic and don't know that there is an option to reverse and they simply think they can figure out what to do on their own, those are the women who are in danger.

REPRESENTATIVE WHITE: Thank you.

MR. CHAIRMAN: Representative Sherrell, you are recognized.

REPRESENTATIVE SHERRELL: Thank you, Chairman.

Thank you, Dr. Boles for being here today.

And my question is I believe you said you never have performed any abortions?

DR. BOLES: Correct.

REPRESENTATIVE SHERRELL: I just want to say you're my kind of doctor, and I appreciate what you stand for and appreciate you being here today,

and I appreciate you protecting life inside the mother's womb. Thank you for being here today.

DR. BOLES: Thank you, sir.

MR. CHAIRMAN: Representative Dixie, you are recognized.

REPRESENTATIVE DIXIE: You referenced two different studies. The one with 754 and the one with 6 or 12. Was the 700- -- the study with the 754, was it conducted under the same conditions as the one with 12? Are we comparing apples to apples here or are they two different studies with two different scopes?

MR. CHAIRMAN: Dr. Boles, you are recognized.

DR. BOLES: They are two different studies conducted by two different people with two different purposes. The first study that I referenced released in 2012 only had six patients and it was not a case controlled-type study. It simply reported a series of six patients in whom reversal was attempted and in whom four of the six were successful.

There were two other small studies that were published, which I don't have with me today. And then there was a final study by the creators of

the reversal regimen that you do have in the folder that I gave you published by Dr. George Delgado in a peer review journal in which he evaluated 754 patients that wished to reverse the effects of the mifepristone. They did not take their Cytotec and they took progesterone in a variety of different regimens. They were randomized to receiving an injection versus an oral regimen and there were different oral regimens that were used.

This study of nearly a thousand patients did show that the most effective regimen is now the one we currently recommend and that it has a 68 percent success rate with no increase in birth defects and no increase in adverse outcomes for the woman.

The final study you've asked about was conducted by an abortion doctor who randomized 12 women that sought an abortion into two groups of six each. Some received the abortion pill only and placebo; some received the abortion pill and the reversal regimen that we currently recommend. Those were the studies that I've referenced.

MR. CHAIRMAN: Representative Dixie, any further question?

REPRESENTATIVE DIXIE: (No audible

response.)

MR. CHAIRMAN: Okay. Thank you.

Chairman Smith, you are recognized.

REPRESENTATIVE SMITH: Thank you, Dr. Boles.

Just as clarification, if this were taken out of the scope of treating abortion, would this be viewed as just simply informed consent, talking with a patient about the options that they have as a standard approach to care if it were removed from the abortion issue? Because I know that's what is so controversial in the minds of many. But if you remove this practice of informing and giving full information to the patient in any other scope of care, would this just be considered informed consent in a standard practice of care?

DR. BOLES: Absolutely. That's -- that is one of my points.

REPRESENTATIVE SMITH: Thank you, Dr. Boles.

DR. BOLES: For example, if a patient comes to me and she wants to have her tubes tied, my informed consent process with her is similar to what should occur with the informed consent process for the abortion pill. I say to her, "Are you sure you

don't want anymore children because you have to consider this method of birth control to be irreversible."

And then I go on to tell her, "You have probably heard of people having their tubes put back together. That is possible but it only works about 50 percent of the time and you can't use this as your method of birth control if you're going to think about doing that in the future. That would not be a good choice." That's my informed consent process before tying a woman's tubes.

In a similar fashion, basic ethical requirements for informed consent on taking an abortion pill should say that if you take this and regret it afterwards, there is a way to try to reverse it. It won't always work, but you can try it and here is how you access that information. That process can be completed, as I just stated in less than 15 seconds and in no way is an undue burden on either the woman or the abortion provider. It's simply medical ethics.

MR. CHAIRMAN: Chairman Smith, you are recognized.

REPRESENTATIVE SMITH: Thank you, Doctor, and thank you Mr. Chairman for sponsoring

this bill. This is good standard of practice and good standard of care, and I think this is an easy vote for this member. Thank you.

Thank you.

MR. CHAIRMAN: Thank you.

Representative Miller, you are recognized.

REPRESENTATIVE MILLER: Thank you, Mr. Chair.

Mr. Chairman, I think last week in subcommittee we heard from a female physician. Will we hear from her while we are out of session?

MR. CHAIRMAN: Thank you. She was supposed to be on the schedule for today. She was on the schedule for last week. And I do not see her in the audience, and I do not know that we have anyone on the other -- that may want to testify while we are out of session.

REPRESENTATIVE MILLER: Thank you, Mr. Chairman.

Doctor, thank you for your presentation.

Do you support a woman's right to choose to have an abortion or not have an abortion?

DR. BOLES: I support the woman's right

to access birth control and to make the decisions about whether or not to become pregnant. But once another life is involved -- because science and ethics are very clear that human life begins at conception -- once another life is involved, I do not support abortion as a human right in any case other than to save the life of the mother, which is an extremely rare occurrence.

MR. CHAIRMAN: Representative Miller, you are recognized.

REPRESENTATIVE MILLER: However, you support the right of the woman to change her mind in a case of reversal? You support her right to choose to change her mind?

DR. BOLES: When she is making the choice to save the life of a child that she thought a moment before that she didn't want then, yes, I support that. Because that choice potentially saves a life. The choice to abort the pregnancy always ends a life. There's a vast difference between those two positions.

MR. CHAIRMAN: Representatives Miller?

REPRESENTATIVE MILLER: Thank you, Mr. Chairman. Thank you.

MR. CHAIRMAN: Thank you.

Representative Cooper, you are recognized.

REPRESENTATIVE COOPER: Thank you Mr. Chairman.

I apologize, everyone. I had to run out to present a bill in another committee and that's why I was not here and I missed part of your presentation.

I want to know -- this pill that is allowed right now it does destroy -- prevents a baby from being born. In other words, it kills the embryo.

DR. BOLES: Yes, it does.

REPRESENTATIVE COOPER: And I know there may be a lot of studies because, like I said, I missed part of your presentation.

If it kills the baby, what does it do to the mother?

DR. BOLES: The application that Danco Pharmaceuticals made to the Food and Drug Administration would lead you to believe that there are very few side effects or adverse outcomes for the mother. However, there have been women who as a result of unusual infections after the use of this medication, and there are many women who have had

bleeding that require transfusion or surgery afterwards.

And, you see, the problem here is that while 29 states require that the complications of abortions be reported to the State's Department of Health or to the Center for Disease Control, 21 states don't require reporting at all. And of the 29 who do, the enforcement mechanisms in those states have no teeth. So we don't have accurate information on how often women experience bad complications from use of this abortion regimen.

There are a number of reports to the Food and Drug Administration of adverse events. But the vast majority of these adverse outcomes and complications were not reported by abortion providers. They were reported by emergency room doctors and private OB/GYNs like myself to the adverse event reporting database. That data with several thousand adverse outcomes is currently being analyzed by a group of which I am a part and we expect publication to occur later this year on a more accurate incidence of adverse outcomes using the medication abortion regimen.

So in answer to your question, yes, there are the potential for bad outcomes for women

who use this medication.

REPRESENTATIVE COOPER: Okay. Earlier you said --

MR. CHAIRMAN: Representative Cooper, you are recognized.

REPRESENTATIVE COOPER: Do you mean that mothers have lost their lives?

DR. BOLES: Some mothers have. A few mothers have lost their lives. Most of those deaths have occurred because of atypical infections that typically are only seen after the use of medication abortion. But there -- there's the potential as well for death from blood loss or other problems.

REPRESENTATIVE COOPER: One moment, Mr. Chair, and I'll be finished.

And with that few, do you have a number?

DR. BOLES: I do not have a number. That's what we're working on. The group that I'm a part of is working on a number.

REPRESENTATIVE COOPER: Thank you, Mr. Chair and thank you for being here.

MR. CHAIRMAN: Thank you.

I have one clarification on something that you answered for her. She had asked if the

first pill, mifepristone, damaged the baby -- I think is what she said. I think -- would it be more clear to say that that pill creates an environment that's not conducive to the baby therefore that damages the baby as opposed to specifically it damaging the baby?

DR. BOLES: The pill -- the intended effect of the pill is to kill the child, and it accomplishes this by interfering with the action of progesterone. That action reduces the blood supply into the uterus which causes the placental tissue to become unstable and it deprives the placenta and the embryo or fetus of oxygen and other critical nutrients. That's the -- if you want to call it, embryocidal or feticidal. That's the feticidal effect.

MR. CHAIRMAN: Thank you.

Representative Dixie, you have another question?

REPRESENTATIVE DIXIE: Yes.

Are you familiar with the report that was produced by the Louisiana Department of Health which did a study based on the effects of abortions induced with drugs and chemicals if they can be reversed and to report the findings to their state

and house committees?

Are you familiar with that?

DR. BOLES: I was not aware that Louisiana had undertaken that.

REPRESENTATIVE DIXIE: Okay. Well, after that study they have several experts -- seven, I think, to be exact -- you know, from medical fields, OB/GYN, pharmacies -- they had an array of panels.

And the conclusion was that there was neither sufficient evidence or a scientific basis to conclude that the abortion induced with drugs or chemicals can be reversed. So I think what you're asking -- to go along with what Representative Clemmons was saying -- we're asking to set a standard on something that cannot be proven that's not safe. And even if you do 754 people at 68 percent of that, I don't think that's representative to be asking people to -- for us to mandate something that's not proven or recommend something that's not proven.

MR. CHAIRMAN: Dr. Boles, you are recognized.

DR. BOLES: To specifically answer that, I would have to see how the Louisiana Department of

Health arrived at their conclusions because I would -- with what you have stated about their conclusions, I would vigorously disagree.

You know, the abortion industry -- you keep focusing on 754 patients not being enough. But the abortion industry and Dr. Creinin want us to conclude that this is not safe based on a series of 12 patients. Which is it?

MR. CHAIRMAN: Representative Dixie, you are recognized.

REPRESENTATIVE DIXIE: I don't want to get confused or lost in confusion. But I just want to make it clear that I believe that the one that was based on the six patients was stopped because of the risk of the health for women. The one at 754, I'm not sure -- I don't think that there's enough information out there to be making this -- to make this a mandate. That is my question.

If one was stopped due to concerns of health of women in this particular trial, I think that there's something that maybe we should take some time to even -- maybe we should look at to get the members to look at the report that the Louisiana Department of Health put forth so we can be a little bit more informed before we make this

decision.

DR. BOLES: In response to that, again, the study was stopped because two of the six women in the group who only took the abortion pill had a bad outcome. The six women in the group that took the progesterone to reverse it did not have bad outcomes. Five of the six had surviving embryos and none of the six required a blood transfusion or a surgery. The only two adverse outcomes were in the group that took the abortion pill without the reversal regimen and one of them required surgery and the other one required surgery and a blood transfusion.

So if we want to draw a conclusion from a series of 12 patients that was stopped, it was stopped because the ones that didn't get the reversal regimen did not do well. That's the real conclusion that you can draw from that study. And from a study of 754 patients that show no increase in bad outcomes for the women who try reversal and show a 68 percent success rate at saving the baby's lives, I think that speaks for itself.

MR. CHAIRMAN: All right. Thank you. I think we got one last -- Chairman [sic] Kumar and then we are going -- I think everybody has had their

questions and we are going to wrap this up.

But, Chairman Kumar, you are recognized.

REPRESENTATIVE KUMAR: Thank you, Mr. Chairman. Thank you for your generosity.

Dr. Boles, thank you for being here.

DR. BOLES: You're welcome.

REPRESENTATIVE KUMAR: I think stopping the study is required as a humane gesture or the responsibility to our patients when the outcomes are so clear. And that's not an uncommon phenomenon, is it?

DR. BOLES: That's correct.

REPRESENTATIVE KUMAR: Providing a patient with full information is part of the informed consent. You know, medication you're taking, can it be the worst, what side effects does it have? That should be a part of the informed consent. And it's very good that we are -- we have legislation to this regard so this process does not get overlooked. But certainly, this should really, in a way, should not be necessary if we were all to inform the patients completely of the effects of what treatment we are giving them and the possibilities of reversal.

These are remorseful and intense in overwhelming times, and these are patients, in my opinion that certainly need complete information and reassurance that it's an uncertain territorial acting and certainly the situation can be rescued if need be, if they change their mind.

My last question to you is is there knowledge within the studies and science at this time about babies that were delivered following the reversal process? How old are they now and are there any health consequences to them?

MR. CHAIRMAN: Dr. Boles, you are recognized.

DR. BOLES: The first one would have been delivered in 2007 or 2008, so we now have a teenager that was successfully reversed. And since then, there are over a thousand reported deliveries and then there are some women who did not follow up. Of the ones that we have been able to follow, of the ones that have been -- that it's been possible to track, there is no increase in the number of problems that the child has from the standpoint of birth defects or developmental issues or behavioral issues. None.

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In fact, the statistic I mentioned earlier gives -- shows another benefit to using this and perhaps that will someday be broadened to all pregnancies. But when you have the preterm delivery rate being around 10 percent with premature delivery being responsible for an enormous number of health care problems and the expenditure of an enormous amount of health care dollars, this regimen appears to reduce the preterm delivery rate from 10 percent down to less than 3 percent.

So there have been no adverse outcomes for the babies noted either development or behavior or birth defects. And there is -- there are two very significant benefits that have been shown. One, saving the baby's life 68 percent of the time. And, two, reducing the preterm delivery rate.

REPRESENTATIVE KUMAR: Thank you, Dr. Boles. We are grateful for your presence and your knowledge. Thank you.

DR. BOLES: Thank you.

MR. CHAIRMAN: All right. Thank you. I appreciate your testimony.

And seeing no further questions, we will go back into session.

We are back on the amendment. We have a -- the question has been called on the amendment without objection. We are voting on Amendment 014982.

All those in favor say "aye."

COMMITTEE MEMBERS: (Collectively) Aye.

MR. CHAIRMAN: Opposed?

COMMITTEE MEMBERS: (No audible response.)

MR. CHAIRMAN: Ayes have it. The amendment goes on the bill.

I believe we have a second amendment by Representative Dixie.

Do you plan to run that amendment?

REPRESENTATIVE DIXIE: If I can explain it.

MR. CHAIRMAN: Okay. It is Amendment 015380.

UNIDENTIFIED SPEAKER: Motion on amendment.

UNIDENTIFIED SPEAKER: Second.

MR. CHAIRMAN: Okay. You have a motion and a second.

REPRESENTATIVE DIXIE: So with the previous amendment, I think there's some signage --

well, with this bill there's going to be some signage that's going to be in waiting rooms or in the physician area. So this will just require some additional language to put a warning to patients that there have been no medical trials completed that prove a medication abortion can be reversed. And that's simply what my amendment does -- add verbiage.

MR. CHAIRMAN: Okay. Chairman Hill, you're recognized on the amendment.

CHAIRMAN HILL: Thank you very much.

In light of the fact that we just spent 50 minutes to the contrary of what this amendment says, I move to table Amendment Number 2.

UNIDENTIFIED SPEAKER: Second.

MR. CHAIRMAN: Okay. Proper motion.

With that, we will be voting on the tabling motion.

All those in favor of tabling Amendment 015380 say "aye."

COMMITTEE MEMBERS: (No audible response.)

MR. CHAIRMAN: Debate is off all except for the sponsor before we go to the tabling motion.

REPRESENTATIVE DIXIE: We did talk about

the clinical trials, but there is nothing that has been successfully proven that this is very effective for women in these trials. I think that it's not sufficient enough, and I think that this verbiage is very important to go on the signage as well.

And with that, that's all I have to say on this and thank you, Mr. Chairman, for giving me a second to speak about this.

MR. CHAIRMAN: Thank you. With that, we will be voting on the tabling motion.

All those -- we are tabling 015380. All those in favor of tabling the amendment, vote "aye."

COMMITTEE MEMBERS: (Collectively) Aye.

MR. CHAIRMAN: Opposed?

COMMITTEE MEMBERS: (Collectively) No.

MR. CHAIRMAN: Ayes have it. We have tabled the amendment.

We are back on House Bill 2568 as amended.

Chairman Faison, you are recognized.

REPRESENTATIVE FAISON: I renew my motion.

MR. CHAIRMAN: Chairman White, you are recognized.

REPRESENTATIVE WHITE: Thank you, Chairman.

Just one more time, based on the question I asked our guest, would you just restate what the signage says in the original bill in the amendment that we just passed?

REPRESENTATIVE FAISON: Thank you, Chairman White.

This bill would provide -- or require abortion facilities to post both signage in the facilities as well as give verbal information to women about the procedure as well as how and where they can procure the abortion pill reversal if they so choose.

MR. CHAIRMAN: Thank you. Representative Clemmons, you are recognized.

REPRESENTATIVE CLEMMONS: Thank you, Mr. Chairman, and thank you sponsor.

I appreciate what I believe is your intent with this legislation. I did raise the issue earlier of false hope. And I have a sincere concern about that, and I know that your intent with this legislation is not to increase the number of women who come in thinking that if they change their mind they can just reverse that. I think

that could be an effect to this legislation that may not be considered for, you know, this body has spent during my tenure a lot of time limiting the constitutional rights of women. And this bill seems to do the reverse of that or could have the effect of doing the reverse of that.

And I'm reading this notice that's to be posted in the doctors' offices, and I think the language of it is very telling because we've talked a lot about the medical studies or lack thereof and sample sizes. And I just want to read this.

"Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid." There seems -- there's a lot of iffy language in this notice.

And this is a pretty thoroughly drafted piece of legislation. You've got down to the font of what it has to say on the website and so forth.

Are you concerned, given what we've heard today, the testimony I think you heard in the subcommittee from both sides and just the language of this legislation that you are providing women who are already in an emotional state making probably, I would argue, the most difficult

decision in their life. Are you concerned you're giving them false hope?

MR. CHAIRMAN: Chairman Faison, you are recognized.

REPRESENTATIVE FAISON: Thank you, Mr. Chairman.

The gentleman from Shelby County -- I mean from Davidson County, I will remind you that two years ago in Washington D.C. in a very bipartisanship manner, every democrat and republican alike in the House and the Senate, which is an extreme rarity, they voted for a law called Right to Try. And that would give Americans the ability to enter in and try some medical treatment that may or may not work. It could possibly give them false hope, but it could also possibly give them hope. I would encourage you that this is not what we're doing here.

This is not 100 percent. Very few things in medicine are 100 percent. But there are times that a young lady -- and I have actually spoken with some -- that they were devastated by what they did, they got scared, they got pressured, by people -- maybe pressured by a perpetrator, and they realized, "You know what, I need a chance. I,

at least, can try to undo this."

And I'm also intrigued that someone such as yourself who is a champion -- so-called champion for women's right to choose, would want to deny them the ability to understand that this is a choice that they can make. This is another choice to provide for them.

So I'm not challenged at all that this isn't 100 percent. I'm encouraged that there is a possibility and that this could save a life and that we're giving a mom another choice.

MR. CHAIRMAN: Represent Clemmons.

REPRESENTATIVE CLEMMONS: Thank you, Mr. Chairman.

And thank you for that response. I guess my concern is to address your last point. Nothing in the law prohibits this from taking place right now. I think it's up to the medical professional's discretion. And right now we are adding something into the standard of care or seeking to -- it appears to add something into the standard of care of medical professionals who, you know, they are not prevented from doing this already.

So I don't think that we are standing

in the way or that the law prohibits this or stands in the way in any respect. And, you know -- and I get that there's two sides to this issue, and I certainly never heard from a woman who has been denied that opportunity. You very well may have as you said.

The other issue I want to address here is we are creating a Class E felony in civil liability even with the award of attorney's fees in this legislation. I assume that's your attempt to put some teeth into this and force medical professionals to comply with it. But, you know, this body has decimated medical malpractice in the State of Tennessee.

And so really the teeth you're seeking to put into it, because of our medical malpractice laws and tort reform, the teeth that I think you're intending to put into this law is virtually nonexistent because of the high hurdles that we have in the State of Tennessee in that respect.

So I just point that out to you, and I don't know that a response is necessary. But thank you very much, and I appreciate your time, Mr. Chairman.

MR. CHAIRMAN: Thank you. Any further

questions?

Seeing none, we are voting on House Bill 2568.

All those in favor, say "aye."

COMMITTEE MEMBERS: (Collectively) Aye.

MR. CHAIRMAN: Ayes have it. The bill moves on to Calendar and Rules.

If you wish to be recorded as a "no" please -- or have your vote recorded, please tell the clerk.

(WHEREUPON, the foregoing proceedings were concluded.)

REPORTER'S CERTIFICATE

STATE OF TENNESSEE

COUNTY OF MONTGOMERY

I, D. ROCHELLE KOENES, Licensed Court Reporter, with offices in Clarksville, Tennessee, hereby certify that I transcribed the audio recording of LEGISLATIVE HISTORY HOUSE HEALTH COMMITTEE - HB2568 by machine shorthand to the best of my skills and abilities, and thereafter the same was reduced to typewritten form by me.

I further certify that I am not related to any of the parties named herein, nor their counsel, and have no interest, financial or otherwise, in the outcome of the proceedings.

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LCR# 689 Expires: 6/30/2021

## D

## E



## F